DEC 30 2013

510(k) Summary

Cayenne Medical, Inc.

SureLock™ All- Suture Anchor

ADMINISTRATIVE INFORMATION

Date of summary:	10/07/2013
Manufacturer Name:	Cayenne Medical, Inc. 16597 N. 92nd St., Suite 101 Scottsdale, AZ 85260 Telephone (480) 502-3661 FAX (480) 502-3670
Official Contact:	Shima Hashemian 16597 N. 92nd St., Suite 101 Scottsdale, AZ 85260 shashemian@cayennemedical.com Telephone (480) 502-3661 FAX (480) 502-3670

DEVICE NAME

Classification Name:	Smooth or threaded metallic bone fixation fastener
Trade/Proprietary Name:	SureLock™ All- Suture Anchor
Common Name:	Suture Anchor

DEVICE CLASSIFICATION

FDA has classified bone screws as Class II devices (21 CFR 888.3040). The product code for Fastener, Fixation, Nondegradable, and Soft Tissue is MBI. These devices are reviewed by the Orthopedic Joint Devices Branch.

INTENDED USE

The Cayenne Medical, Inc. SureLock™ All- Suture Anchor is intended to reattach soft tissue to bone in orthopedic surgical procedures. The system may be used in either arthroscopic or open surgical procedures. After the anchor is deployed in the bone, the floating sutures can be used to reattach soft tissue, such as ligaments, tendons, or joint

capsules to the bone. The suture anchor system thereby stabilizes the damaged soft tissue, in conjunction with appropriate postoperative immobilization, throughout the healing period.

The Cayenne Medical, Inc. SureLock™ All-Suture Anchors are intended to be used for the reattachment of soft tissue to bone for the following indications:

Shoulder
- Capsular stabilization
  - Bankart repair
  - Anterior shoulder instability
  - SLAP lesion repairs
  - Capsular shift or capsulolabral reconstructions
- Acromioclavicular separation repairs
- Deltoid repairs
- Rotator cuff repairs
- Biceps tenodesis

Foot and Ankle
- Hallux valgus repairs
- Medial or lateral instability repairs/reconstructions
- Achilles tendon repairs/reconstructions
- Mid and forefoot reconstructions
- Metatarsal ligament/tendon repairs/reconstructions
- Bunionectomy

Elbow
- Ulnar or radial collateral ligament reconstruction
- Lateral epicondylitis repair
- Biceps tendon repair

Hand and Wrist
- Collateral ligament repair
- Scapholunate ligament reconstruction
- Volar plate reconstruction
- Tendon transfers in phalanx

Hip
- Acetabular labral repair

Knee
- Extra-capsular repairs
  - Medial collateral ligament
  - Lateral collateral ligament

  - Posterior oblique ligament
- Patellar realignment and tendon repairs
- Illiotibial band tenodesis
- VMO advancement
- Joint capsule closure

DEVICE DESCRIPTION

The SureLock™ All-Suture Anchor is a sterile (using ethylene oxide sterilization method), manually operated, single procedure all suture anchor device for reattachment of soft tissue to bone. The all-suture anchor is preloaded with floating suture and loaded on a disposable inserter. SureLock™ All-Suture Anchor incorporates design features that facilitate suture anchor placement under arthroscopic, open, or limited access conditions in soft tissue to bone reattachment procedures.

The SureLock™ All-Suture Anchor is offered in two different sizes, 1.4mm and 2.2mm. The anchors and floating sutures are made out of non-absorbable Ultra High Molecular Weight Polyethylene (UHMWPE) surgical sutures.

The 1.4mm anchor is formed by passing one end of a length of suture perpendicularly back through itself in alternating directions a number of times. This results in a construct resembling a ladder. The four suture tails are cut and trimmed. A floating suture is passed through the loops in the anchor to form the anchor construct.

The 2.2mm anchor is formed by passing the end of a first length of suture through the core of a second length. Then, one end of the second length is passed through the core of the first length, creating a loop with four suture tails. The loop is twisted alternately a number of times with the floating sutures weaved through each twist to form the anchor construct.

The 1.4mm anchor is pre-loaded with one floating suture and the 2.2mm size is pre-loaded with two floating sutures.

The following table summarizes the two configurations of the All-suture Anchor device.

Catalog number	All-Suture anchor size	Anchor-suture size and color	Floating suture size	Number of floating sutures	Floating suture type and color
CM-9614	1.4 mm	USP size 2 - White	USP size 2	1	Co-braid Black/white, or co-braid blue/white, or co-braid green/white, or solid blue
CM-9622	2.2 mm	USP size 2- White	USP size 2	2	a combination of any two colors; co-braid Black/white, or co-braid blue/white, or co-braid green/white, or solid blue

The disposable inserter has a working shaft length of 22.2 cm with an outer shaft diameter of 2.0 mm for the 1.4mm SureLock anchor and 2.4mm for the 2.2mm SureLock anchor. The inserter shaft is made out of surgical grade stainless steel and the handle and knob are made out of ABS plastic. The inserter pushes the suture anchor construct into a hole drilled in the bone. The knob on the inserter handle is rotated to apply tension on the floating suture(s) to expand and deploy the anchor in the bone tunnel. The floating suture limbs are then released from the inserter and the inserter is removed.

NON-CLINICAL TESTING

Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence is included. Mechanical testing (pull-out strength) was performed on the SureLock™ All-Suture Anchor and the predicate device. Testing showed that the SureLock™ All-Suture Anchor ultimate pull-out strength was comparable to that of the predicate device.

EQUIVALENCE TO MARKETED PRODUCT

Cayenne Medical, Inc. demonstrated that, for the purposes of FDA's regulation of medical devices, the SureLock™ All-Suture Anchor is substantially equivalent in indication and design principles to predicate devices, each of which has been determined by FDA to be substantially equivalent to preamendment devices: ConMed Linvatec Y-Knot™ All-Suture Anchor (K111779), Riverpoint Medical HS Fiber Polyblend non-absorbable surgical suture (K100006), and Teleflex Medical ForceFiber® sutures

(K040472, K070673, K092533, and K100506). The substantial equivalence of SureLock™ All-Suture Anchor is based on similarities in indications for use, intended use, design features, technology, and materials to the predicate device.

The subject SureLock device has the same intended use as the predicate device, the ConMed Linvatec Y-Knot™. The predicate device has a broad indication for use stated as "to reattach soft tissue, such as ligaments, tendons, or joint capsules to the bone." The subject device is indicated for a subset of the predicate device's indications for use. The subject device has a narrower indication for use than the predicate device. Cayenne Medical tested both predicate and subject devices for the range of the subject device indications using three bone block densities.

This subject device differs from the predicate device, Conmed Linvatec Y-Knot™, in terms of the All-Suture anchor construction, the inserter role during deployment, and the offered sizes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 30, 2013

Cayenne Medical, Incorporated
Ms. Shima Hashemian
Quality Engineering Manager
16597 North 92nd Street, Suite 101
Scottsdale, Arizona 85260

Re: K132867
Trade/Device Name: SureLock™ All- Suture Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: October 2, 2013
Received: October 3, 2013

Dear Ms. Hashemian:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

Device Name: SureLock™ All- Suture Anchor

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- VMO advancement
- Joint capsule closure

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.
Division of Orthopedic Devices